ECHA
EUROPEAN CHEMICALS AGENCY

[redacted]

26. 01. 2015

Prospective Applicant:

[redacted]

Sent via encrypted email and registered mail

Copy to Data Owner:

[redacted]

Sent via encrypted email and registered mail

Reference number of the dispute claim	DSH-63-3-[redacted]-2014
Decision number	DSH-63-3-D-[redacted]-2014
Name of active substance disputed	Reaction mass of [redacted] (EC [redacted] and [redacted] (EC [redacted])

DECISION RELATING TO YOUR DATA SHARING DISPUTE UNDER ARTICLE 63(3) OF THE BIOCIDAL PRODUCTS REGULATION (EU) No 528/2012 (BPR)

Dear Ms [redacted],

On 23 October 2014, you (the Prospective Applicant) submitted a claim concerning the failure to reach an agreement on data sharing with [redacted] (the Data Owner) as well as the related documentary evidence to the European Chemicals Agency (ECHA). Data sharing had been sought for an application to be included on the Article 95 list as a supplier of an active substance that has not yet been approved. The Data Owner is listed in the Article 95 list as a participant in the review programme for product types 6, 11, 12 and 13.

To ensure that both parties are heard and that ECHA can base its assessment on the complete factual basis, ECHA also requested the Data Owner to provide documentary evidence regarding the negotiations. The Data Owner submitted the requested documentary evidence on 20 November 2014.

On 16 January 2015, ECHA informed you of the outcome of its assessment and informed you that it would issue a permission to refer to the studies if you provide a proof of payment; the proof of payment amounting to [redacted] EUR was provided on 23 January 2015. ECHA has no competence to assess the "proportionate share of the cost", which may eventually be determined by a competent national court.

Based on the documentation supplied by both parties, ECHA has decided to grant you permission to refer to the studies requested from the Data Owner for the above-mentioned active substance.

[redacted]

The permission to refer concerns the studies listed in **Annex I** to this decision. The statement of reasons of this decision is set out in the **Annex II**.

In accordance with Articles 63(5) and 77(1) of the BPR, an appeal against this decision may be brought to the Board of Appeal of ECHA within three months of the notification of this decision. The procedure for lodging an appeal is described at http://echa.europa.eu/web/guest/regulations/appeals.

Yours sincerely,

[redacted]

Geert Dancet
Executive Director

Annexes:

Annex I: List of studies subject to the dispute, to which ECHA grants the permission to refer

Annex II: Statement of reasons of the decision of of the data sharing dispute

[redacted]

Annex I to decision DSH-63-3-D-[redacted]-2014

LIST OF STUDIES SUBJECT TO THE DISPUTE, TO WHICH ECHA GRANTS THE PERMISSION TO REFER[1]

1	[redacted]
2	[redacted]

[1] Based on the explicit request of the Prospective Applicant, dated 23 January 2015, the scope of the data sharing dispute – and hence the scope of the present decision - has been limited to a permission to refer to the two studies indicated in the present annex.

Annex II to decision DSH-63-3-D-[redacted]-2014

STATEMENT OF REASONS OF THE DECISION OF THE DATA SHARING DISPUTE

Article 63(1) of the BPR requires the Prospective Applicant(s) and the Data Owner(s) to "*make every effort to reach an agreement on the sharing of the results or studies requested*". Further, according to Article 63(4), "*[c]ompensation for data sharing shall be determined in a fair, transparent and non-discriminatory manner*". If no agreement can be reached, Article 63(3) mandates ECHA on request to "*give the prospective applicant permission to refer to the requested tests or studies, provided that the prospective applicant demonstrates that every effort has been made to reach an agreement and that the prospective applicant has paid the data owner a share of the costs incurred*". On this basis, ECHA conducts an assessment serving to establish whether the parties have fulfilled their legal obligation to make every effort to share the studies and their related costs. The assessment is based on the information provided by the Prospective Applicantant and the Data Owner.

The documentation shows that the discussions between the Prospective Applicant and the Data Owner on the sharing of data for reaction mass of [redacted] (EC [redacted]) and [redacted] (EC [redacted]) predate the entry into operation of the BPR. However, this assessment only takes into account the period between 1 September 2013 and 23 October 2014, i.e. from the entry into application of the BPR until the submission of the dispute claim to ECHA[2], because data sharing provisions of the BPR only applied as of this date.

The key element of the negotiations between the Prospective Applicant and the Data Owner which prevented the parties from reaching an agreement was the assessment of technical equivalence (TE).

Factual background

In their email dated 16 September 2013, the Data Owner requested that TE be assessed as a "basis" for the data sharing negotiations. The Prospective Applicant agreed to an assessment of TE by a consultant in their email of the same day. Subsequently, the parties decided to first investigate whether the French Evaluating Competent Authority would be able to assess TE.[3] However, in their email of 18 November 2013, the Prospective Applicant informed that France had declined to assess TE and that they were now in discussion with ECHA for this purpose.

On 18 November 2013, the parties concluded an "every effort and secrecy agreement under the biocidal products regulation for [redacted]". Apart from clauses regarding confidentiality, the parties agreed, *inter alia* to have TE assessed at the prospective applicant's cost by either ECHA, the rapporteur Member State, or a technical consultant before data are shared.

With their message of 6 December 2013, the Prospective Applicant quoted ECHA stating that "data owners do not have the right to demand any form of similarity check as a prerequisite for getting a letter of access". In spite of this, the Prospective Applicant stated "we agree to the establishment of technical equivalence / similarity", but in light of ECHA's message requested the Data Owner to share in the costs. Further, they proposed three

[2] For further information, see also question "[911] What if negotiations have started before 1 September 2013?" in ECHA's Q&A section, available at http://echa.europa.eu/support/qas-support/qas;
[3] Cf. the Prospective Applicant's email dated 23 September 2013;

consultants who could perform the TE assessment, and the prospective Applicant did not pursue his suggestion to share the cost of TE further.

With their email dated 11 December 2013, the Data Owner asked whether they could suggest alternative consultants, and with their message of 17 December 2013 made two proposals of laboratories they worked with on TE in the past. However, they did not react to the Prospective Applicant's suggestion to share the costs of the TE assessment.

In their reply of 9 January 2014, the Prospective Applicant underlined that they would have to pay for the TE assessment and have no experience with the consultants suggested by the Data Owner, and therefore asked the Data Owner to reconsider if they could agree to any of the initial suggestions.

On 16 January 2014, the Data Owner asked if the Prospective Applicant's experience with the consultants they had suggested was on TE assessments.

With their email dated 31 January, the Prospective Applicant agreed to [redacted] ("the Institute") assessing TE, i.e. one of the consultants that the Data Owner had proposed. On 6 February 2014, the Prospective Applicant informed the Data Owner that a contract with the Institute had been concluded and that the Prospective Applicant's sample for the TE assessement had been forwarded to the Institute. Further, they now requested the Data Owner to provide their sample to the Institute as well.

The Data Owner had not come to a confidentiality agreement with the Institute by late March 2014 and, consequenetly, did not provide a sample to the Institute. Therefore, the Prospective Applicant wrote in their email of 25 March 2014 that "we have done all that you wanted to find a common way. We agreed to do this assessment and we agreed to your proposed consultant" and asked the Data Owner "to make a workable proposal how to proceed until 1.4.2014".

While the Prospective Applicant repeatedly asked the Data Owner to respect their agreement[4], the Data Owner refused to provide the Institute with their sample for the TE assessment.

Instead, on 30 June 2014, the Data Owner wrote that they had carried out their own analysis of market samples of the Prospective Applicant's products and had detected impurities. Based on these findings, the Data Owner considered that the Prospective Applicant's material is not technically equivalent.

In their reply of the same day, the Prospective Applicant requested that the contract be fulfilled, i.e. that the Data Owner send their information to the Institute. They wrote that the Data Owner did not specify which materials where analysed, what kind of analysis was performed and what the result was, and therefore considered these findings as irrelevant. Further, the Prospective Applicant announced that in case the Data Owner should not send their data to the Institute by 4 July 2014, ECHA would be informed of the failure of negotiations.

With their message dated 3 July 2014, the Data Owner agreed that all conditions had been fulfilled by the Prospective Applicant to proceed with the TE assessment. They wrote that "regular samples from the market" were used for the analysis, which was not conducted under GLP standards but could still "clearly identify these substances". As the Prospective Applicant would not have asked which impurities had been found, the Data Owner considers

[4] Cf. the Prospective Applicant's emails dated 16 and 23 July 2014;

that the Prospective Applicant is aware of them and their "toxic properties". Therefore, the Data owner argued that before providing their data to the Institute, the Prospective Applicant needed to take a position regarding the impurities. Finally, they pointed out that TE is in the mutual interest of both parties and serves to ensure that only products complying with the quality requirements are on the market.

In their reply dated 8 July 2014, the Prospective Applicant wrote that the Data Owner still had not indicated the product name, batch number, methods or results. They referred to the contract that they had concluded, and insisted that this be respected. According to this agreement, the Institute shall assess TE. Therefore the Institute shall receive the necessary data. They further outlined that the Data Owner's refusal to provide the data to the Institute was a breach of contract, and set a deadline of 24 July 2014 to do so.

On 23 July 2014, the Data Owner wrote, *inter alia*, that they considered it their duty to clarify descrepancies between the samples of the Prospective Applicant purchased on the market and their own samples for the sake of the market, the final user, ECHA and the Prospective Applicant. They want to ensure that only material that complies with the quality requirements, for which the risk management measures are designed, is placed on the market.

When the dispute was lodged, the Data Owner had not forwarded their data to the Institute.

Assessment

ECHA notes that the parties made considerable efforts to overcome disagreements on several issues, such as the conclusion of a Best Efforts Agreement including the deposit payment by the Prospective Applicant, the review of the Data Owner's studies by the Prospective Applicant's toxicologist, and the cost of data. ECHA notes that in those matters the parties succeeded to overcome their differences and to reach an agreement.[5]

Consistency and reliability of the negotiating parties are crucial to making "every effort" to reach an agreement in accordance with Article 63(1) of the BPR. This means that a party should stand by its earlier requests and arguments, and not overturn its position once its demands are met. This does not mean that a party can never change its position. However, if it changes its point of view or demands during the negotiations, it is part of making "every effort" to explain the reasons for this change of mind.

In the case at hand, the prior assessment of TE[6] by a third party was a demand by the Data Owner, and it was a concession by the Prospective Applicant to agree to such an assessment at their own expense. As the parties discussed during the negotiations, TE is not a legal requirement for data sharing under the BPR. A data owner cannot unilaterally make it a prerequesite for data sharing.

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[5] Cf. the Prospective Applicant's emails dated 26 September 2013, 30 October 2013, 18 November 2013, 9 January 2014, 31 January 2014, 6 February 2014, 26 March 2014, 9 April 2014, 22 April 2014, 14 May 2014, 21 May 2014, 16 June 2014, 17 June 2014, 19 June 2014, 23 June 2014, 26 June 2014, 1 July 2014, 2 July 2014, 4 July 2014, 7 July 2014, 28 July 2014, and 11 August 2014; Cf. the Data Owner's emails dated 23 September 2013, 7 October 2013, 23 October 2013, 15 November 2013, 4 December 2013, 16 January 2014, 19 March 2014, 26 March 2014, 15 April 2014, 29 April 2014, 20 May 2014, 17 June 2014, 30 June 2014, 2 July 2014, 3 July 2014, 4 July 2014, 23 July 2014, and 28 July 2014;

[6] For clarification, the parties referred to TE to describe the chemical similarity of their substances. TE as defined in the BPR can only be concluded on when the active substance is approved. See http://echa.europa.eu/regulations/biocidal-products-regulation/technical-equivalence and http://echa.europa.eu/regulations/biocidal-products-regulation/chemical-similarity-check-service

Further to the arguments exchanged in the negotiations, ECHA observes that proof of TE, as assessed by ECHA, will be required for the eventual application for product authorisation. In order to obtain an indication whether the data obtained will be relevant for the product authorisation, a prospective applicant may wish to make data sharing conditional upon a prior assessment of TE (i.e. chemical similarity by an independent consultant). However, a data owner cannot unilaterally make TE a precondition for data sharing. When data is shared for the purposes of Article 95 BPR, a data owner merely obtains a share of the cost. There is thus no detriment to data owner in sharing data, even if the prospective applicant's substance is not technically equivalent. A data owner cannot bring reasons of public interest to refuse data sharing, such as claiming that he has to ensure that quality standards are respected or risk management measures apply. Those tasks are undertaken by the relevant authorities of the Member States in the public interest, in accordance with national rules as provided by Article 89(2) BPR and subject to the appropriate procedural rights and guarantees.

The choice of the Institute to perform the TE assessment was based on a proposal by the Data Owner. When the Data Owner subsequently insisted instead that they discuss the impurities of the product of the Prospective Applicant (i.e. TE) on the basis of a study that the Data Owner had carried out themself, they did not provide any justification for the unilateral breach of the contractual agreement and change of opinion or why the independent laboratory of their choice should no longer be suitable to establish the TE. The parties' decision to have a neutral third party assess the TE was designed to ensure the acceptance of the result by both parties. Indeed, the Data Owner's subsequent insistence on discussing TE on the basis of a test that they carried out unilaterally and the details of which they did not disclose, defeats the logic of the previous demands.

This change, which was not explained, shows a lack of reliability and consistency, and thereby constitutes a lack of efforts which resulted in the failure to reach an agreement.

On the other hand, the Prospective Applicant had made every effort to find an agreement. For example, they had agreed to the TE assessment by the Institute at their own cost as demanded by the Data Owner in spite of not being obliged by the BPR to ensure technical equivalence until the submission of an application for product authorisation, had forwarded their data to the Institute and kept the negotiations going by displaying flexibility and providing prompt replies.

Based on the above, ECHA concludes that the Prospective Applicant made every effort, while the Data Owner did not make every effort to reach an agreement to share the data. Consequently, ECHA grants the Prospective Applicant permission to refer to the tests and studies requested from the Data Owner pursuant to Article 63(3) BPR.

Further observations

As noted above, a mutual agreement to establish TE by an independent third party prior to data sharing for the purpose of an active substance under Article 95 of the BPR might very well be in the interest of the parties, particularly the Prospective Applicant, because it provides an indication whether the data under negotiation can actually be of use for their own substance. Therefore, in spite of the permission to refer granted with this decision, the parties are encouraged to continue their data sharing negotiations and to proceed with the TE assessment by the Institute as agreed earlier.